

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP,
KBI INC, and KBI-E INC.

Plaintiffs and
Counterclaim Defendants,

v.

Civil Action No. 3: 11-cv-00760-JAP-TJB

HANMI USA, INC., HANMI
PHARMACEUTICAL CO., LTD., HANMI
FINE CHEMICAL CO., LTD, and HANMI
HOLDINGS CO., LTD.,

Defendants and
Counterclaim Plaintiffs.

**DECLARATION OF MAUREEN M. JAPHA IN SUPPORT OF PLAINTIFFS' BRIEF IN
SUPPORT OF PLAINTIFFS' MOTION FOR INJUNCTION PENDING APPEAL**

I, Maureen M. Japha, declare as follows:

1. I am an associate at the law firm of Covington & Burling, LLP, 1201 Pennsylvania Ave, NW, Washington, DC 20004, counsel for Plaintiffs' AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc. in connection with the present action.

2. I make this Declaration on my personal knowledge in support of Plaintiffs' Brief in Support of Plaintiffs' Motion for a Preliminary Injunction.

3. Attached as Exhibit A, is a true and correct copy of an August 7, 2013 Yonhap News Agency article entitled: "U.S. FDA Oks sale of S. Korea's improved version of Nexium"
(available at: <http://www.globalpost.com/dispatch/news/yonhap-news-agency/130807/us-fda->

oks-sale-s-koreas-improved-version-nexium) (last visited, August 20, 2013).

4. Attached as Exhibit B is a true and correct copy of U.S. Patent No. 5,714,504.
5. Attached as Exhibit C is a true and correct copy of excerpts from the File History of U.S. Patent No. 5,714,504, bearing Bates numbers HAN0039508-HAN0040299.
6. Attached as Exhibit D is a true and correct copy of an excerpt from NDA No. 202342, produced with Bates numbers HAN000441-HAN0000444.
7. Attached as Exhibit E is a true and correct copy of a November 26, 2012 Report from KDB Daewoo Securities entitled, “Earnings surprise from domestic recovery, strong API exports.”
8. Attached as Exhibit F is a true and correct copy of an April 9, 2009 Report from Bank of America/Merrill Lynch entitled, “Downgrade; expectations built up, but risks ignored.”
9. Attached as Exhibit G is a true and correct copy of an Investor Relations report, available on Hanmi’s website, where it is identified as “2009 1Q Result – IR Presentation File” (*available at:* www.hanmipharm.com/eng/investors/quarterly.asp?yy=2009).
10. Attached as Exhibit H is a true and correct copy of a May 5, 2013 MK Business News article by Sae-bom Lee, entitled “Hanmi Pharmaceutical’s Drug Obtains Tentative Approval from US FDA” (*available at:* <http://news.mk.co.kr/newsRead.php?year=2013&no=346884>) (last visited August 19, 2013).
11. Attached as Exhibit I is a true and correct copy of an August 8, 2013 article from the Korea Economic Daily, entitled: “Hanmi Pharm Gets IMD Permission from the US FDA,” (*available at:* english.hankyung.com/news/apps/news.view?popup=0&nid=&c1=04&nkey=201308080722221) (last visited August 20, 2013).

12. Attached as Exhibit J is a true and correct copy of an August 8, 2013 article from the Korea IT Times, entitled: “Hanmi Pharm Gets IMD Permission from the US FDA,” (*available at:* koreaittimes.com/story/31030/hanmi-pharm-gets-imd-permission-us-fda) (last visited August 20, 2013).

13. Attached as Exhibit K is a true and correct copy of an August 8, 2013 Hanmi press release, entitled “Hanmi’s Incrementally Modified Drug, Esomezol, Enters US market” (*available at:* www.hanmipharm.com/eng/release/board_read.asp?seq=652&board_id=7).

14. Attached as Exhibit L is a true and correct copy of the November 7, 2011 Declaration of Dr. Stephen G. Davies on Claim Construction.

15. Attached as Exhibit M is a true and correct copy of excerpts from the December 16, 2011 deposition of Dr. Jerry L. Atwood, Ph.D.

16. Attached as Exhibit N is a true and correct copy of the May 16, 2013 Final Pretrial Order in the above-captioned case.

17. Attached as Exhibit O is a true and correct copy of Hanmi’s proposed draft labeling, produced with Bates numbers HAN0000098-HAN0000121.

18. Attached as Exhibit P is a true and correct copy of excerpts from the April 26, 2013 deposition of Dr. Jerry L. Atwood, Ph.D.

19. Attached as Exhibit Q is a true and correct copy of excerpts from NDA No. 202342, produced with Bates numbers HAN0002757-HAN0002758.

20. Attached as Exhibit R is a true and correct copy of excerpts from NDA No. 202342, produced with Bates numbers HAN0000831-HAN0000833.

21. Attached as Exhibit S is a true and correct copy of a February 7, 2013 letter from

Parexel to FDA, regarding NDA 202342, produced with Bates numbers HAN0372373-HAN0372374.

22. Attached as Exhibit T is a true and correct copy of an August 6, 2013 letter from FDA to Hanmi USA, Inc.

23. Attached as Exhibit U is a true and correct copy of excerpts from the November 16, 2012 deposition of Kyu Chan Kwon.

24. Attached as Exhibit V is a true and correct copy of an Investor Relations report, available on Hanmi's website, where it is identified as "2013 2Q Result – IR Presentation File" (*available at:* www.hanmipharm.com/eng/investors/quarterly.asp).

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 20, 2013



Maureen M. Japha